Also the term silicone in claim 10 has been replaced with biocompatible material.

Drawings:

Fig 1 is a new drawing showing new replacement of the previous Fig 1. The cylindrical cuff (13) made of biocompatible material which encircles the venous outflow catheter (11) and is surgically anastamosed to the arterial inflow graft (12). The venous outflow catheter has a diameter 1mm smaller than the arterial graft. The cuff directs the passage of blood from the arterial graft to the venous outflow catheter. The cuff defines a graded interior diameter to provide a secure fit for both the arterial graft and the venous outflow catheter. Figure 2 and 3 will remain the same as previous and are provided.

RESPONSES

Reponse to Rejections of claims 1-5,7-10,12-14,17, and 18 under 35 USC. 103(a) as being unpatenable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

With respect to claims 1-5 in the art of making a hemodialysis apparatus, claims 1-5 describe the arterial inflow graft which is connected to the artery with surgical anastamosis. This is an essential part of the Khan Arteriovenous hybrid shunt and this remains common to all ateriovenous shunts commonly being used and that will be used in future art. From the arterial inflow graft, the blood is taken to the dialysis machine where the blood is purified and then directed through the venous side of the shunt. This is a common component for all hemodialysis shunts which are being used in current art and will be used in the future inventions. The invention of new art is dependent on the position of the arteriovenous graft or venous outflow catheter on the venous side. If claims 1-5 are rejected then all current and future inventions since 1966 [including Squitieri's] when the arteriovenous shunt was first described by Brescia et al. are unpatenable, which is clearly not the case.

The arterial graft that Squitieri attaches to the connector (20) in Fig. 7 of US 6,102,884 is not the same as our cuff. This is a metal chamber with a membrane which is used for needle access. Our cuff [See Fig.1] connects the arterial inflow graft to the venous outflow catheter and defines a graded interior diameter to provide a secure fit for both the arterial graft and the venous outflow catheter. Therefore our cuff is completely different from the needle connector site of Squitieri. This cannot be a reason for the rejection of our claims.

Further the venous outflow catheter of Squitieri [See Fig. 6-9] makes it very clear that his

venous outflow catheter remains in the unnamed vein. In our invention the venous outflow catheter does not remain in the vein. It is passed through the veins into the right atrium of the heart, which is a large muscular chamber. The blood is directly deposited into this chamber and the complications of neointimal hyperplasia and graft failure is abolished.

It is unreasonable to suggest that Squiteri's catheter can be advanced to the right atrium, because Squitieri does not even himself mention the names of the veins that he puts his own catheter in. Any change or repositioning of his venous catheter will invalidate his invention, because his own written intention was for the position of his catheter to be into the vein. Squiteiri has not mentioned the right jugular vein, vena cava or the right atrium.

The examiner cannot mention that Squitieri's invention can be placed in the right jugular vein, vena cava or the right atrium and function in these areas which are not ever mentioned by even Squitieri. This was mentioned on page 7 and 8 of the Office Action Summary dated 10/26/07. In our invention the catheter is not in the vein.

It is on the other hand positioned in the right atrium and the two inventions are therefore different and the rejections should therefore be withdrawn.

It may be further submitted that the device and the method disclosed by Squitieri would perform differently than that claimed by the applicant. In Squitieri's invention the blood is injected into the veins under high pressure and the veins which are thin walled, leading to neo-intimal hyperplasia and graft failure.

Parks et al , US 5,399,173, describes a ferrule or connector (see Fig 7) which is a

connector to be used in the construction of a gastrostomy tube or feeding tube. This tube is to be inserted into the stomach. This cannot be compared to our cuff which is used the the construction of an arteriovenous shunt. A person of ordinary skill in the art of vascular surgery and creation of a novel arteriovenous shunt could never consider using a ferrule which is designed for feeding tube for fluid handling and not directing blood under pressure. This connector is absolutely different from the inventors cuff and cannot be used in the construction of an arteriovenous shunt. Parks' art belongs to the gastrointestinal system in the construction of a feeding tube and our invention is intended for construction of AV shunts in the arteriovenous system.

With regards to our claims 2, 3, and 7; tubing 69 (See Fig. 8 of Squitieri's art) is made of a PTFE graft which is attached to the artery as already described. Our invention also uses this PTFE graft or other biocompatible material for connection to the artery. This a common component of any arteriovenous shunt and cannot the basis for any rejection of claims 2,3 and 7. Therefore it is requested that rejections to claims 2,3, and 7 be withdrawn

With responses to rejected claim 10, this has been amended; the central venous catheter will be made of polyurethane or biocompatible material.

With regard to rejections for claim 13, it describes the components of our arteriovenous shunt which is used for performing the hemodialysis. Many other arts which are currently used and patented are used in this way for hemodialysis-they cannot all be made invalid.

An arteriovenous shunt is intended for dialysis of the patient and in our art we have created an arteriovenous shunt for dialysis of the patient. Squitieri cannot be the only

claimant of the arteriovenous shunt method for dialysis. Therefore claim number 10 cannot be rejected.

With regard to rejections for claim 17, Squitieri describes that the blood is taken from the arterial graft to the dialysis machine and returned to the patient via the venous catheter into the veins. In our invention, we also take blood from the arterial graft and connect it to the dialysis machine and the purified blood via the venous outflow catheter into the right atrium. The difference being the blood is ejected into the unnamed veins in Squitieri's invention and to the right atrium in our invention and therefore our new art is different from Squitieri's. Therefore, the rejection to claim 17 needs to be withdrawn.

Reponse to Rejections of claims 6,11,15,16,19, and 20 under 35 USC. 103(a) as being unpatenable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,591,226 to Trerotola et al.

The Squiteri and Parks inventions are totally different as described earlier. The Trerotola (US 5,591,226) invention describes a stented graft deployed connecting the brachial artery and axillary vein [see fig 9a]. The graft has barbed wires which fixes the grafts to the axillary artery and axillary vein. Therefore this shunt is a brachio-axillary shunt with ends fixed to the artery and vein, incapable of any advancement. In our invention we use different arteries as specified in claim 19. The primary difference between Trerotola and our invention is that Trerotola uses a stented graft and makes a sutureless anastamosis in the artery and vein with barbed wires attached to the graft ends. The blood is therefore directly injected into the axillary vein. In our invention, there is no anastamosis of the venous outflow catheter to any vein and the blood is directly deposited into the right atrium as the catheter sits in the right atrium. In Trerotola's invention the graft is also a stented graft, whereas in our invention we use a stentless graft. He also inserts the graft

into the axillary vein and in our invention we do not use a graft for insertion into the right atrium, we use a venous outflow catheter. The combined reference of Squitieri, Parks and Trerotola are not properly combined references and modification thereof do not still provide the Applicants claimed invention. Therefore the rejections for claims 6,11,15,16,19 and 20 can be respectfully withdrawn.

CONCLUSION

Applicants submit that a full and complete response has been made to the Office Action. Thus a prompt and favorable consideration is respectfully requested. If the examiner believes that personal communication will expedite prosecution of this application, please call me directly at (312) 730-8796. Thank You.

Dated 1/13/08

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